REMARKS

Power Of Attorney

Applicant's agent Mary Anthony Merchant has withdrawn from representation of Applicant. The assignee of the entire interest in and to this Application, Cygene, Inc., appoints Craig G. Cochenour, Esq., Reg. No 33, 666, George P. Baier, Reg. No. 26,717, Michael L. Dever, Reg. No. 32,216, and Lynn J. Alstadt, Reg. No. 29,362 of Buchanan Ingersoll, P.C. as its attorneys. A Revocation Of Power Of Attorney Or Authorization Of Agent form is attached and a Power Of Attorney Or Authorization Of Agent form is attached along with a Statement Under 37 CFR 3.73 (b).

Election/Restriction

In view of the Examiner's earlier restriction requirement, Applicant's prior election is without prejudice to Applicant's right to file a divisional patent application for non-elected Claims 3, 5, 9 and 11 at a later date.

Information Disclosure Statement

Applicant acknowledges the Examiner's statement concerning the proper use of form PTO-892 in a information disclosure statement.

Claim Objections

Claim 1 was objected to because of the informality that the claim as originally written contained an abbreviation, namely "ICP". Applicant has amended Claim 1 by inserting before the abbreviation the phrase "inactive complement peptide". Applicant believes that Claim 1 as amended is now in acceptable form as requested by the Examiner.

Claim Rejections-35 USC §112

Claims 1, 2, 4, 6-8, 10, and 12 were rejected under 35 USC §112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that Claims 1, 8 and 12 are vague and indefinite because the preamble of the claims does

not match with the methods steps since there is no detection step in the claims. Applicant has amended Claims 1, 8 and 12, and Claims 2, 4, 6, 7, and 10 that depend from amended Claims 1 and 8, respectively, by adding a step in the Claims that recites detecting a target analyte, carcinogen, and cancerous cell. Applicant believes that the goal of the Claims as amended is clear, and the Applicant respectfully requests that this rejection be withdrawn.

Claim Rejections- 35 USC § 102

Claims 1, 2, 4, 7, 8, 10 and 12 were rejected under 35 USC § 102 (b) as being anticipated by Juhl et al. (Cancer Research Suppl., Vol. 55, pages 5749s-5755, December 1, 1995). As amended, Applicant's Claims recite methods for detection of one or more specific target analytes, carcinogens, and cancerous cells in a sample comprising providing a sample and treating the sample with at least one antibody specific to an antigenic marker on the target analyte, carcinogen, and cancerous cell for forming a complex that fixes at least one complement molecule, activating the complement cascade for producing at least one inactive complement peptide (ICP), amplifying the production of the inactive complement peptide by employing at least one lipid membrane, measuring the presence of ICP, and detecting the target analyte, carcinogen and cancerous cell wherein the quantity of ICP is directly proportional to the number of target analyte, carcinogen, and cancerous cell in the sample.

The Applicant respectfully submits that the claimed methods for detection of one or more specific target analytes, carcinogens or cancerous cells in a sample including amplifying the production of ICP by employing a lipid membrane are not taught or suggested by Juhl et al. Juhl et al. teaches a method of infiltrating a cancerous pancreatic tumor by forming a particular monoclonal antibody (mab) cobra venom factor (CVF) conjugate, namely CA19-9-CVF, having tumor-binding properties, and activating the alternate pathway of complement targeted to a pancreatic solid tumor tissue. Juhl et al. is concerned with increasing the uptake of a monoclonal antibody-CVF conjugate into solid tumors for providing adjuvant immunotherapy to a patient. It is important to note that Juhl et al. does not teach methods of detecting low copy number target analytes, carcinogens or cancerous cells in a sample via the classical complement cascade wherein

the sample also has non-target material and wherein the method includes the step of amplifying the production of an inactive complement peptide (ICP) . Juhl et al. is unconcerned in providing signal amplification of inactive complement peptides (ICP), such as C2a, C3a, C4a, and C5a.

Juhl et al. states that in contrast to human C3, the cobra venom factor CVF leads to a permanent activation of complement cascade because the activity of the cobra venom factor CVF can not be inhibited by complement inhibitor factors H and I. Juhl et al. is interested in producing an inflammatory response and attracting immunocytes and macrophages to a tumor tissue site. Juhl et al. teaches way from the presently claimed invention wherein Juhl et al. states that complement-cell lysis could not be achieved by applying the monoclonal antibody cobra venom factor CA19-9 CVF (see Juhl et al., right column, page 5749s, second full paragraph). The Examiner's statement that "CA19-9 CVF conjugate [was known] induced complement-mediated cell lysis, as well as cytotoxic mab, which activated the classical pathway of complement" is therefore in error as it relates to the CA19-9 CVF as set forth in Juhl et al. As stated hereinbefore, Juhl et al. states that CVF alone activates the alternative pathway of complement (left column, page 5754s, third full paragraph). Juhl et al.'s statement that some "mab-CVF conjugates" (excluding CA19-9 CVF) "induce complement-meditated cancer cell lysis" (in human neouroblastoma cells), and that "cytotoxic mab activates the classical pathway" is focused upon the teaching of Juhl et al. that mab-CVF conjugates, including CA19-9 CVF, can improve the infiltration of NK cells and macrophages in a pancreatic cancer model. In contrast, the invention set forth in the present claims recite methods for detection of a target analyte, carcinogen , or cancerous cells including amplifying the production of an inactive complement peptide (ICP). Juhl et al. is not only unconcerned with methods of detecting a target analyte, carcinogen or cancerous cell in a sample, but also does not teach and does not suggest the importance of amplifying the production of an inactive complement peptide as recited in the claims of the present invention.

CONCLUSION

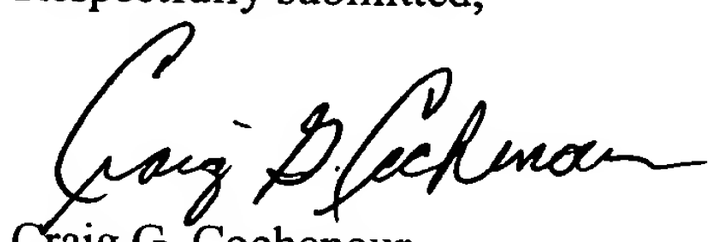
It is respectfully submitted that Applicant's claims, as amended, illustrate patentable methods not taught or suggested by any of the art of record. Applicants believe that the amendments and remarks set forth in this paper place this Application in a condition for allowance and such action is respectfully requested at an early date. If the Examiner believes that personal communication will expedite the prosecution of this Application, the Examiner is invited to telephone the Applicant's undersigned attorney directly.

AUTHORIZATION

Applicant's believe that a three month extension of time is required for the submission of this Response and Amendment, and Applicant attaches a Petition for Three Month Extension Of Time. Applicant believes that no further government fees are due for amendments made to the claims of this Application.

The Commissioner is hereby authorized to charge any necessary additional fees for the extension of time or additional fees associated with this paper to Deposit Account No. 02-4553. A duplicate copy of this Response and Amendment is enclosed for deposit account purposes.

Respectfully submitted,



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